

**REMARKS****I. Introductory Remarks**

Applicants respectfully request reconsideration of this application in view of the foregoing amendments and the following remarks.

Upon entry of the foregoing amendments, claims 1-8, 11, 26-34, 36, 38-39, 41 and 44-45 will be pending in the application, with claims 1-8, 11, 27-34, 36, 38-39 and 41 being withdrawn from consideration. Currently, claim 21 is being canceled, claim 26 is being amended, and claims 44-45 are being added.

The table below shows where the specification contains exemplary support for the amendments to claim 26 and for new claims 44-45.

<b>Claim</b>	<b>Exemplary Support</b>
26	Original claim 21; Page 9, line 20 – page 10, line 2; Page 12, lines 1-16.
44	Page 13, lines 1-4
45	Page 13, lines 6-7

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

**II. Restriction Requirement**

The Office has made its restriction requirement final. Applicants respectfully request reconsideration of that decision.

For reasons set forth in the Response filed on May 9, 2003, the restriction requirement is improper. Claims 21, 26-30, and 41 all are linked by a common inventive concept, namely

the specific xylanase inhibitors and/or use thereof to identify xylanases having a specific degree of resistance thereto.

In partial recognition of this fact, the Office joined claims 21 and 26 in Group III. Applicants submit that the Office further should join claims 27-30 to Group III because claims 27-30 each depend from claim 26. The principles of “unity of invention” dictate that if an independent claim has unity of invention, claims depending therefrom also have unity of invention. See MPEP AI-63, Administrative Instructions under the PCT, Instructions Concerning Unity of Invention (attached).

### **III. Priority**

The Office acknowledged Applicants’ claim for foreign priority, but has not granted priority because Applicants allegedly have not provided the foreign priority document UK 9828599.2. Applicants request reconsideration of this position.

Certified copies of all three priority documents, including GB9828599.2, were filed with the International Bureau on February 9, 2000 (copy of Applicants’ cover letter is enclosed). The International Bureau acknowledged receipt of these priority documents on form PCT/RO/199, dated February 15, 2000 (copy of the acknowledgement is enclosed).

This application therefore merits the benefit of priority to UK 9828599.2.

### **IV. The Claims Comply with 35 U.S.C. § 112, Second Paragraph**

Claims 21 and 26 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for the recitations “obtainable from” and “(if at all).” Claim 26 also was rejected for containing the step of “determining the extent to which the inhibitor inhibits the activity of the xylanase,” rather than “determining the degree of resistance [to the xylanase inhibitor.]” Applicants respectfully traverse these rejections.

First, the phrase “obtainable from” has a clear meaning and therefore is not indefinite. As used in the specification, an inhibitor “obtainable from wheat” is an inhibitor that exists in wheat, but also may exist in other sources, such as barley. Thus, an inhibitor “obtainable from wheat” simply is an inhibitor endogenous to wheat. To emphasize this point, Applicants have

substituted “endogenous to” for “obtainable from” in claim 26. This substitution does not change the meaning of the claim, and therefore does not introduce new matter into the application.

Second, Applicants have deleted the phrase “(if at all)” from the claims. This deletion does not affect the scope or meaning of the claims.

Third, the step of “determining the extent to which the inhibitor inhibits the activity of the xylanase of interest” is proper. This step implicitly relates to determining whether the xylanase has “a high degree of resistance” to the xylanase inhibitor. Indeed, it is axiomatic that to determine if a xylanase has a high degree of resistance to an inhibitor, one must determine the extent to which the inhibitor inhibits the xylanase. Nevertheless, Applicants have amended claim 26 to recite that in performing the method steps, one is “thereby identifying one or more xylanases having a high degree of resistance to the inhibitor.” This amendment obviates the rejection, without changing the scope of the claim.

#### **V. The Claims are Patentable over the Cited Art**

Claims 21 and 26 were rejected under 35 U.S.C. § 102(a) as being allegedly anticipated by four separate references: (1) Debyser et al., *J. Cer. Sci.*, 30: 39-43 (1999) (“Debyser 1”); (2) Debyser et al., *J. Am. Soc. Brew. Chem.*, 55(4): 153-156 (1997) (“Debyser 2”); (3) WO 98/49278 (“Debyser 3”); and Rouau et al., *J. Cer. Sci.*, 28: 63-70 (1998) (“Rouau”). However, none of these references anticipate the pending claims.

##### **A. Debyser 1 Does not Anticipate the Claims as it is not Available as a Prior Art Reference**

Debyser 1 does not constitute prior art as defined in 35 U.S.C. § 102(a). The reference was published after all three of this application’s British priority documents were filed. Therefore, Applicants request withdrawal of the rejection based on Debyser 1.

##### **B. Debyser 2 does not anticipate the claims**

Debyser 2 describes experiments in which the endoxylanolytic activity of malt extracts, measured in the presence of wheat water extracts, provided evidence for the presence of one

or more endoxylanase inhibitors in wheat that are inactivated by heat. It was shown that these wheat inhibitors do not inactivate a *Bacillus subtilis* endoxylanase.

Significantly, the reference discloses the use of a wheat *extract*, and not an *isolated* xylanase inhibitor. By contrast, the claimed invention relates to a method using an isolated xylanase inhibitor for determining the degree of resistance of a xylanase to the inhibitor. The method comprises determining the extent to which the inhibitor inhibits activity of the xylanase, as a means for discovering xylanases having a high degree of resistance to the inhibitor. Debyser 2 does not teach or suggest such a method. Regarding claim 45, Debyser 2 additionally fails to teach or suggest that isolated xylanases resistant to a xylanase inhibitor are useful for preparing dough.

**C. Debyser 3 Does not Teach or Suggest the Claimed Invention**

Debyser 3 relates to an inhibitor of xylanolytic and/or  $\beta$ -glucanolytic enzymes and to the use of such an inhibitor in food, feed and/or beverage technologies. The inhibitor is described as being useful for improving malting and brewing and for making baked and/or extruded cereal products.

The reference does not teach or suggest, however, that the isolated inhibitor is useful to specifically identify and prepare one or more xylanases having a high degree of resistance to the inhibitor. Additionally, the reference fails to teach or suggest that xylanases resistant to the inhibitor are useful for preparing dough.

**D. Rouau Does not Teach or Suggest the Claimed Invention**

Rouau contains evidence indicating the presence in wheat grain of a water-extractable and thermolabile compound that inhibits exogenous hemicellulases.

Like Debyser 2, however, Rouau pertains to an aqueous *extract*, and not an *isolated* xylanase inhibitor. By contrast, the claimed invention relates to a method using an isolated xylanase inhibitor for determining the degree of resistance of a xylanase to the inhibitor. The method comprises determining the extent to which the inhibitor inhibits activity of the xylanase, as a means for discovering xylanases having a high degree of resistance to the

inhibitor. Rouau does not teach or suggest such a method. Further, Rouau does not teach or suggest that isolated xylanases resistant to a xylanase inhibitor is useful for preparing dough.

Because none of the cited references teach or suggest the claimed methods, Applicants request withdrawal of the art-based rejections.

**VI. Concluding Remarks**

The application is now in condition for allowance, and favorable reconsideration thereof is respectfully requested.

If the Examiner believes that an interview would advance prosecution of the application, he or she is invited to contact the undersigned by telephone.

The Commissioner is hereby authorized to charge any additional fees that may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date Nov 25, 2003

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## **MPEP AI-63**

### **Administrative Instructions under the PCT, Instructions Concerning Unity of Invention**

ANNEX B

UNITY OF INVENTION

PART 1

INSTRUCTIONS CONCERNING UNITY OF INVENTION

(a) **Unity of Invention.** Rule 13.1 deals with the requirement of unity of invention and states the principle that an international application should relate to only one invention or, if there is more than one invention, that the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept.

(b) **Technical Relationship.** Rule 13.2 defines the method for determining whether the requirement of unity of invention is satisfied in respect of a group of inventions claimed in an international application. Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any).

(c) **Independent and Dependent Claims.** Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).

(i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. Moreover, no

problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.

(ii) If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity *a posteriori* (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation.

(iii) This method for determining whether unity of invention exists is intended to be applied even before the commencement of the international search. Where a search of the prior art is made, an initial determination of unity of invention, based on the assumption that the claims avoid the prior art, may be reconsidered on the basis of the results of the search of the prior art.

(d) **Illustrations of Particular Situations.** There are three particular situations for which the method for determining unity of invention contained in Rule 13.2 is explained in greater detail:

(i) combinations of different categories of claims;

(ii) so-called "Markush practice"; and

(iii) intermediate and final products.

Principles for the interpretation of the method contained in Rule 13.2, in the context of each of those situations are set out below. It is understood that the principles set out below are, in all instances, interpretations of and not exceptions to the requirements of Rule 13.2.

Examples to assist in understanding the interpretation on the three areas of special concern referred to in the preceding paragraph are set out below.

(e) **Combinations of Different Categories of Claims.** The method for determining unity of invention under Rule 13 shall be construed as permitting, in

## MANUAL OF PATENT EXAMINING PROCEDURE

particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or

(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or

(iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product and an independent claim for an apparatus or means specifically designed for carrying out the said process, it being understood that a process is specially adapted for the manufacture of a product if it inherently results in the product and that an apparatus or means is specifically designed for carrying out a process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art.

Thus, a process shall be considered to be specially adapted for the manufacture of a product if the claimed process inherently results in the claimed product with the technical relationship being present between the claimed product and claimed process. The words "specially adapted" are not intended to imply that the product could not also be manufactured by a different process.

Also an apparatus or means shall be considered to be "specifically designed for carrying out" a claimed process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art. Consequently, it would not be sufficient that the apparatus or means is merely capable of being used in carrying out the claimed process. However, the expression "specifically designed" does not imply that the apparatus or means could not be used for carrying out another process, nor that the process could not be carried out using an alternative apparatus or means.

(f) **"Markush Practice."** The situation involving the so-called "Markush practice" wherein a single claim defines alternatives (chemical or non-chemical)

is also governed by Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity, and

(B)(1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

(ii) In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art. The structural element may be a single component or a combination of individual components linked together.

(iii) In paragraph (f)(i)(B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

(iv) The fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention.

(v) When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised.



## ADMINISTRATIVE INSTRUCTIONS UNDER THE PCT

(g) **Intermediate and Final Products.** The situation involving intermediate and final products is also governed by Rule 13.2.

(i) The term “intermediate” is intended to mean intermediate or starting products. Such products have the ability to be used to produce final products through a physical or chemical change in which the intermediate loses its identity.

(ii) Unity of invention shall be considered to be present in the context of intermediate and final products where the following two conditions are fulfilled:

(A) the intermediate and final products have the same essential structural element, in that:

(1) the basic chemical structures of the intermediate and the final products are the same, or

(2) the chemical structures of the two products are technically closely interrelated, the intermediate incorporating an essential structural element into the final product, and

(B) the intermediate and final products are technically interrelated, this meaning that the final product is manufactured directly from the intermediate or is separated from it by a small number of intermediates all containing the same essential structural element.

(iii) Unity of invention may also be considered to be present between intermediate and final products of which the structures are not known—for example, as between an intermediate having a known structure and a final product the structure of which is not known, or as between an intermediate of unknown structure and a final product of unknown structure. In order to satisfy unity in such cases, there shall be sufficient evidence to lead one to conclude that the intermediate and final products are technically closely interrelated as, for example, when the intermediate contains the same essential element as the final product or incorporates an essential element into the final product.

(iv) It is possible to accept in a single international application different intermediate products used in different processes for the preparation of the final product, provided that they have the same essential structural element.

(v) The intermediate and final products shall not be separated, in the process leading from one to the other, by an intermediate which is not new.

(vi) If the same international application claims different intermediates for different structural parts of the final product, unity shall not be regarded as being present between the intermediates.

(vii) If the intermediate and final products are families of compounds, each intermediate compound shall correspond to a compound claimed in the family of the final products. However, some of the final products may have no corresponding compound in the family of the intermediate products so that the two families need not be absolutely congruent.

(h) As long as unity of invention can be recognized applying the above interpretations, the fact that, besides the ability to be used to produce final products, the intermediates also exhibit other possible effects or activities shall not affect the decision on unity of invention.

(i) Rule 13.3 requires that the determination of the existence of unity of invention be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

(j) Rule 13.3 is not intended to constitute an encouragement to the use of alternatives within a single claim, but is intended to clarify that the criterion for the determination of unity of invention (namely, the method contained in Rule 13.2) remains the same regardless of the form of claim used.

(k) Rule 13.3 does not prevent an International Searching or Preliminary Examining Authority or an Office from objecting to alternatives being contained within a single claim on the basis of considerations such as clarity, the conciseness of claims or the claims fee system applicable in that Authority or Office.

**[ANNEX B, CONTINUED]**

**PCT/RO/199 DATED FEBRUARY 15, 2000**

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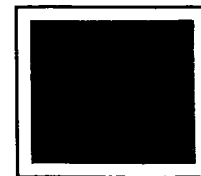
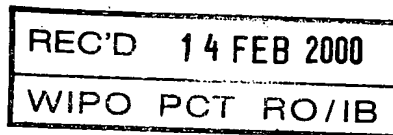
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For the Attention Of: Jean-Luc Baron

9 February 2000

Dear Sirs

**International (PCT) Patent Application No PCT/IB99/02071  
Danisco A/S**

We refer to the Form PCT/RO/106 dated 5 January 2000, the response term for which was kindly extended to one month, and file herewith the following documents:

- completed Appointment of Agent forms for each of the applicants;
- formal drawings, in triplicate, to replace the formal drawings as filed;
- certified copies of UK Application Nos 9828599.2, 9907805.7 and 9908645.6 from which the present application claims priority

We trust that we have now dealt with all of the objections raised by the Form PCT/RO/106. Please contact the undersigned if this is not the case.

Please acknowledge receipt of this letter by stamping and returning the enclosed copy.

Yours faithfully  
for D Young & Co

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# PATENT COOPERATION TREATY

PCT/IB99/02071

PCT

ACKNOWLEDGEMENT OF RECEIPT OF  
DOCUMENTS FILED WITH THE  
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To:

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IMPORTANT COMMUNICATION

Date of mailing:  
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Applicant's or agent's file reference  
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International application No.  
PCT/IB99/02071

International filing date (day/month/year)  
17 December 1999 (17.12.99)

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Title of the invention  
PROTEINS

4. The International Bureau has received the documents/elements listed below on: 14 February 2000 (14.02.00)  
by the following means: delivery service

- ☐ PCT Request
- ☐ description (excluding sequence listing part)
- ☐ claims
- ☐ abstract
- ☒ drawings (22 pages) (replacement sheets)
- ☐ sequence listing part of description
- ☐ fee calculation sheet
- ☐ separate authorization to charge deposit account
- ☐ cheque
- ☐ cash (in person only)
- ☒ power(s) of attorney (separate power: 3)
- ☐ statement(s) explaining lack of signature
- ☒ priority document (3)
- ☐ separate indications concerning deposited micro-organism or other biological material
- ☐ nucleotide and/or amino acid sequence listing on diskette
- ☐ statement(s) accompanying diskette(s) containing sequence listing
- ☒ accompanying letter (1)
- ☐ form PCT/RO/198 (RO/IB)
- ☐ other (specify):

Additional observations (if necessary):

Name and mailing address of the receiving Office  
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Chemin des Colombettes, 1211 Geneva 20, Switzerland  
Telex No. (41-22) 910 06 10 (Groups 3 and 4)  
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